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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/789,536

02/26/2004

Arthur M. Krieg

C1039.70083US05

9640

7590 05/24/2011  
Helen C. Lockhart, Ph.D.  
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EXAMINER

MINNIFIELD, NITA M

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

05/24/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/789,536	<b>Applicant(s)</b> KRIEG ET AL.
	<b>Examiner</b> N. M. MINNIFIELD	<b>Art Unit</b> 1645

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 37,39-45 and 47-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 45 and 54-56 is/are allowed.
- 6) ☒ Claim(s) 37,39 and 47-53 is/are rejected.
- 7) ☒ Claim(s) 40-44 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br/>Paper No(s)/Mail Date <u>3/4/11</u>.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)<br/>Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
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Art Unit: 1645

**DETAILED ACTION*****Response to Amendment***

1. Applicants' amendment filed March 4, 2011 is acknowledged and has been entered. Claims 1-36, 38 and 46 have been canceled. Claims 37, 39-45 and 47-56 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment to the claims and/or comments, with the exception of those discussed below.

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 1645

3. Claims 37, 39 and 47-53 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27-31 and 33-39 of U.S. Patent No. 7576066. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application and issued patent claims are directed to a method of administering an antigen (i.e. vaccine) and immunostimulatory oligonucleotide adjuvant to a subject. It is noted that the claimed SEQ ID NO: 1 of 7576066 comprises four unmethylated cytosine-guanine dinucleotides.

Applicant's arguments filed March 4, 2011 have been fully considered but they are not persuasive. Applicants have asserted that "The instant claims are not properly rejected under the doctrine of obviousness type double patenting over US 7,576,066 because US 7,576,066 and the instant patent application are not commonly owned and do not have identical inventive entities. An obviousness type double patenting rejection is inappropriate in this situation. Obviousness type double patenting relates to common ownership. As stated in MPEP 804IIB 1 "Obviousness-type double patenting requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent, or a non-commonly owned patent but subject to a joint research agreement." (emphasis added). An obviousness-type double patenting rejection requires the subject application and cited patent to be commonly owned, rather than to be commonly assigned. According to MPEP 706.02(1) the "term 'common ownership' means wholly owned by the same person(s) or organization(s) at the time the invention was made." The instant patent application is owned by the University of Iowa Research Foundation, Coley Pharmaceutical Group (now owned by Pfizer), and the United States Government as represented by the Secretary, Department of Health and Human Services, and the inventors are Krieg, Klinman, and Steinberg. US 7,576,066 is owned by Coley Pharmaceutical Group (now owned by Pfizer) and the inventor is Krieg. The University of Iowa Research Foundation and the United States Government are not owners of US 7,576,066. Although the patent application and the patent have one common inventor and no owners in common, the application and patent are not commonly owned (common ownership requires all of the

Art Unit: 1645

same owners). An obviousness-type double patenting rejection requires the subject application and cited patent to be commonly owned. Thus, it is requested that the rejection be withdrawn.” (Remarks, pp. 5-6)

However, it is noted that MPEP 800, see Chart II-B allows for a ODP rejection when there are different inventions, not patentably distinct, having a different inventive entity, at least one common inventor (i.e. Krieg) and no common assignee. It is the Examiner’s position that the criteria have been met, although the instant application and issued patent are not commonly owned/assigned they do have *at least one common inventor (i.e. Krieg)*. The ODP rejection is appropriate. There is no indication of a Joint Research Exclusion under 103(c).

4. Claims 45 and 54-56 are allowed.
5. Claims 40-44 are objected to because they depend from a rejected claim.
6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1645

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. MINNIFIELD whose telephone number is (571)272-0860. The examiner can normally be reached on M-F (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

N. M. MINNIFIELD  
Primary Examiner  
Art Unit 1645

/N. M. MINNIFIELD/  
Primary Examiner, Art Unit 1645